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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,646	10/27/2003	Ko-Pen Wang	2607-0003	8915

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DAVIDSON BERQUIST JACKSON & GOWDEY LLP
4300 WILSON BLVD., 7TH FLOOR
ARLINGTON, VA 22203

EXAMINER

APANIUS, MICHAEL

ART UNIT PAPER NUMBER

3736

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/693,646	Applicant(s) WANG, KO-PEN	
	Examiner Michael Apanius	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11172003</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:
 - a. At paragraph 22, line 5, "directional nipple 36" should be --directional nipple 30--.
 - b. At paragraph 33, line 7, "formal" should be --formed--.
 - c. At paragraph 36, line 2, "needle 102" should be --needle 18--.
 - d. At paragraph 37, line 1, "stylet 18" should be --stylet 20--.

Appropriate correction is required.

Claim Objections

2. Claims 7 and 8 are objected to because of the following informalities: at claim 7, line 2 and at claim 8, line 1, "second" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 14-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claims 19-25 are unclear because the dependency of these claims is uncertain. Claims 19-25 as recited depend from claim 1. However, claim 1 does not support the language used in claims 19-25. For example, at claim 19, line 2, "the sampling device" lacks antecedent basis because "a sampling device" is not previously recited in claim 1. The other independent claim 13 contains recitations of the language used in claims 19-25. Therefore, for the purpose of this office action, claims 19 and 22-24 will be treated as if they depend from claim 13.

6. At line 1 of claims 14-25, the first recitation of "The device" lacks proper antecedent basis. Note that claim 13, line 1, recites "A tissue collection device" and that claim 13, line 9 recites "a sampling device".

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang (US 4,966,162).

9. In regards to claim 1, Wang discloses a medical device (figure 13; column 11, line 40 - column 12, line 47), comprising: a flexible outer tubular member (210) having proximal and distal ends; a flexible inner member slidably received within the flexible outer tubular member, the flexible inner member comprising a stylet (308) adjacent the

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proximal end of the outer tubular member, a first spring section (distal half of 302) having proximal and distal ends and being oriented adjacent the distal end of the outer tubular member, and a second spring section (proximal half of 302 including multiple gaps 318) coupled to the stylet and the proximal end of the first spring section; and a hollow needle member (304) coupled to the distal end of the first spring section, wherein the device has a retracted position wherein the needle member is retractably housed within the outer tubular member, a first extended position wherein the needle member is at least partially deployed beyond the distal end of the outer tubular member and the second spring section is in an uncompressed state, and a second extended position wherein the second spring section is in a compressed state. Note that the second spring section is coupled to the stylet by coaxially surrounding the stylet. Furthermore, note that the second spring section will not be compressed until a limiting member (312) contacts a hard tip (222). Therefore, the needle member can be partially deployed without compression of the second spring section. Upon further deployment of the needle member in the distal direction, the spring will begin to compress when the limiting member (312) begins to contact the hard tip (222)

10. In regards to claim 2, the device has a hard tip (222) rigidly fixed to the distal end of the outer tubular member, the tip including a bearing surface on the proximal end thereof.

11. In regards to claim 3, the needle member includes a limiting member (312) rigidly secured at a point along the length of the needle member and contacting the bearing surface of the tip member in the first and second extended positions

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12. In regards to claim 4, the device has a locking member (the threads of 124) securing the inner member into a contacting relationship with the bearing surface to prevent retractable movement of the needle member when in the second extended position.

13. In regards to claim 5, the first spring section comprises a first wavelength and the second spring section comprises a second wavelength (across multiple gaps 318) greater than the first wavelength in the retracted and first extended positions.

14. In regards to claim 6, the second spring section comprises a third wavelength (when the second spring section is compressed) in the second extended position, the third wavelength being less than the second wavelength.

15. In regards to claim 7, the inner member comprises a biasing member (126) biasing the inner member into a contacting relationship with a second bearing surface (on 124) to prevent retractable movement of the needle member when in the retracted position.

16. In regards to claim 8, the second bearing surface is adjacent the proximal end of the outer tubular member.

17. In regards to claim 9, the second spring section forms an inner volume and the stylet passes therethrough.

18. In regards to claim 10, the first spring section forms an inner volume and the stylet extends at least partially into the inner volume thereof in the retracted position.

19. In regards to claim 11, the first spring section forms an inner volume and the stylet passes through the inner volume in the second extended position.

20. In regards to claim 12, the stylet extends into the needle member in the second extended position.

21. In regards to claims 13-25, the limitations are similarly met as stated above in regards to claims 1-12.

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

23. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

24. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

25. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 10/693,645. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claim is broader than the copending application claim. The copending application claim contains many more elements and is therefore more specific. In effect, the copending application claim is a species of the instant application claim. It has been held that the generic invention is "anticipated" by the "species".

26. In regards to the instant application claim 1, the copending application recites a medical device (claim 1, line 1), comprising: a flexible outer tubular member (claim 1, line 2) having proximal and distal ends; a flexible inner member slidably received within the flexible outer tubular member, the flexible inner member comprising a stylet (claim 1, line 5) adjacent the proximal end of the outer tubular member, a first spring section (claim 5, line 1) having proximal and distal ends and being oriented adjacent the distal end of the outer tubular member, and a second spring section (claim 5, line 2) coupled to the stylet and the proximal end of the first spring section; and a hollow needle

member (claim 1, line 11) coupled to the distal end of the first spring section, wherein the device has a retracted position wherein the needle member is retractably housed within the outer tubular member, a first extended position wherein the needle member is at least partially deployed beyond the distal end of the outer tubular member and the second spring section is in an uncompressed state, and a second extended position wherein the second spring section is in a compressed state (claim 1, lines 16-22; claims 6 and 7).

27. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

28. Claim 13 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 10/693,645. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application claim is broader than the copending application claim.

29. In regards to the instant application claim 13, the copending application recites a tissue collection device (claim 14, line 1), comprising: an elongated outer flexible hollow catheter (claim 14, line 2) having proximal and distal ends; an elongated member (claim 14, line 5) slidably positioned within the hollow catheter and defining an axis along its length; a helically wound wire member (claim 14, line 6) having proximal and distal ends and being coaxially attached to the elongated member, wherein the wire member has a proximal region having a first wavelength (claim 16), and a distal region having a

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second wavelength normally smaller than the first wavelength (claim 16); and a sampling device (claim 14, line 8) attached to the distal end of the helically wound wire member.

30. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

31. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,041,082 discloses a mechanical atherectomy system and method.

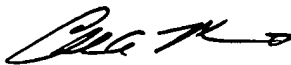
32. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8:30am-5pm.

33. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA


CHARLES MARMOR
PRIMARY EXAMINER